

Food and Drug Administration, HHS

§ 524.1044g

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 47363, Aug. 5, 2004, as amended at 77 FR 64717, Oct. 23, 2012]

§ 524.1044d Gentamicin and betamethasone ointment.

(a) *Specifications*. Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—(i) *Otitis externa*. Instill 3 to 8 drops into the ear canal twice daily for 7 days.

(ii) *Infected superficial lesions*. Apply to cover the treatment area twice daily for 7 to 14 days.

(2) *Indications for use*. For the treatment of acute and chronic otitis externa and infected superficial lesions caused by bacteria sensitive to gentamicin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 26378, June 18, 1982, as amended at 52 FR 7832, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014]

§ 524.1044e Gentamicin spray.

(a) *Specification*. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 1.07 milligrams of gentamicin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount*. Hold the sprayer upright 3 to 6 inches from the affected eye, with the opening directed towards the eye, and pump once. Treat once daily for up to 3 days.

(2) *Indications for use*. For the treatment of pinkeye in cattle (infectious bovine keratoconjunctivitis) caused by *Moraxella bovis*.

(3) *Limitations*. Conditions other than bacterial infections of the bovine eye and infectious keratoconjunctivitis caused by *Moraxella bovis* may produce similar signs. If conditions persists or

increases, discontinue use and consult a veterinarian.

[48 FR 41157, Sept. 14, 1983, as amended 52 FR 7833, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014]

§ 524.1044f Gentamicin and betamethasone spray.

(a) *Specifications*. Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram (mg) gentamicin base and betamethasone valerate equivalent to 0.284 mg betamethasone.

(b) *Sponsors*. See Nos. 000061, 054925, 058005, 058829, and 065531 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer two spray actuations two to four times daily for 7 days.

(2) *Indications for use*. For the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006, as amended at 72 FR 5929, Feb. 8, 2007; 74 FR 22822, May 15, 2009; 77 FR 3598, Jan. 25, 2012]

§ 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.

(a) *Specifications*. Each gram (g) of ointment contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base, betamethasone valerate equivalent to 1 mg betamethasone, and 10 mg clotrimazole.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(1) No. 000061 for use of 7.5- or 15-gram tubes, 12.5-, 30-, or 215-g bottles.

(2) No. 054925 for use of 7.5- or 15-g tubes; 10-, 15-, 25-, or 215-g bottles.

(3) No. 000859 for use of 10-, 20-, 40-, or 215-g bottles.

(4) No. 025463 for use of 7.5- or 15-g tubes, or 215-g bottles.

(c) *Conditions of use in dogs*—(1) *Amount*. Instill ointment twice daily into the ear canal for 7 consecutive days.